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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,646	09/18/2001	Seth A. Foerster	END-777	8823
34263 7590 07/30/2007 O'MELVENY & MYERS LLP 610 NEWPORT CENTER DRIVE 17TH FLOOR NEWPORT BEACH, CA 92660			EXAMINER ROZANSKI, MICHAEL T	
			ART UNIT 3768	PAPER NUMBER
			MAIL DATE 07/30/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/954,646

Applicant(s)

FOERSTER ET AL.

Examiner

Michael Rozanski

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 25 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50,51,55-60,62 and 65-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 50,51,55-60,62 and 65-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date See Continuation Sheet.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

Continuation of Attachment(s) 3. Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date
:7/25/06,7/25/06,7/25/06,10/3/05.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 7/25/06 have been fully considered but they are not persuasive. While the examiner agrees that Shiber does not teach of "no part of the marker extending outside of the body", it is respectfully asserted that Campbell et al '936 is the reference used to teach this feature (referring to subcutaneous penetration, see col. 1, lines 33-43). With respect to the Applicant's argument that there is no motivation to combine the references, this is also refuted as the Shiber reference is specifically used to teach the use of an imaging system to guide that insertion of a marker such as x-ray or ultrasound or making the marker radio-opaque, and not particularly the manner in which the device is released through a side port. Therefore, the previous rejection is maintained and restated below and made FINAL.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims **50-51, 55-60, 62, and 65-67** are rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell et al. '936 of record in view of Kandany '613 (US Patent No. 5,562,613) and Shiber '540 (US Patent No. 5,195,540).

Campbell et al.'936 teach an introducer for inserting a marker element into a particular tissue element having an introducer with a tube having a lumen an axial opening at the proximal end of the tube (see in Figure 10, plunger 18), a side exit port at the distal end of the port (see Figure 15 below, element 22) with at least one discrete marker positioned in the tube (see Figure 18 showing a marker cartridge assembly for delivering markers at the area of interest) and a shaft extending from the axial opening and ejecting the marker from the side exit port by the application of compressive force (referring to the plunger 18 pushing the marker 30; see col. 4, lines 24-58) such that no marker element extends outside the body (referring to subcutaneous penetration; see col. 1, lines 33-43).

Campbell et al.'936 do not teach a closed distal end and a side exit port defining a plane, the plane being parallel to the longitudinal axis of the tube, wherein the side exit port is located adjacent a distal end of said tube.

In the same field of endeavor, Kaldany'613 teaches a closed distal end and a side exit port defining a plane, the plane being parallel to the longitudinal axis of the tube, wherein the side exit port is located adjacent a distal end of said tube for the introduction of pellets of interest (see Figure 7 and respective specification description in col. 5, lines 22-34).

It would have been obvious to one skilled in the art at the time that the invention was made to have modified Campbell et al.'936 and incorporated the teaching of Kaldany'613 in order to alter the end of the catheter to have a closed distal end with a side exit port defining a plane, the plane being parallel to the longitudinal axis of the

tube, wherein the side exit port is located adjacent a distal end of said tube in order to enable the physician to advance the marker at the area of interest with greater precision once the side port has been aligned with the tissue of interest by allowing for a simple unidirectional handed motion (see for motivation to combine Kaldany'613, col. 2, lines 45-49).

Campbell et al.'936 further teaches a plurality of markers capable of being introduced (see col. 7, line 65- col. 8, line 16).

The use of expandable markers to further enhance attachment to the tissue of interest while allowing for easier transfer through the lumen and the variety of materials used for such markers as long as they are biocompatible are well known functional equivalents to skilled artisans.

Campbell et al.'936 in view of Kaldany'613 teach all the elements of the current invention except for the use of an imaging system to guide the insertion of a marker such as x-ray or ultrasound or making the marker radio-opaque.

In the same field of endeavor, Shiber'540 teaches an imaging system to guide the insertion of a marker such as x-ray or ultrasound (see col. 1, lines 4-23; and especially lines 20-23). It would have been obvious to one skilled in the art at the time that the invention was made to have modified Campbell et al.'936 in view of Kaldany'613 and incorporated the teaching of Shiber' 540 because if the area of interest for insertion of the marker (spiral wire marking the tissue) is human tissue such as breast imaging is necessitated to avoid further trauma to the patient by accurately guiding the marker at the location of interest (see for motivation to combine in

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Shiber'540 col. 2, lines 21-26).

In the same field of endeavor, Shiber'540 teaches making the marker radio-opaque or of any material allowing visualization by the imaging modality of interest (see col. 2, lines 7-14).

It would have been obvious to one skilled in the art at the time that the invention was made to have modified Campbell et al.'936 in view of Kandany'613 and incorporated the teaching of Shiber'540 because that would increase the visibility of the guided procedure and accurate visualization of the positioning of the marker at the area of interest.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


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5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Rozanski whose telephone number is 571-272-1648. The examiner can normally be reached on Monday - Friday, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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